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EXAMINER

MEHTA, BHISMA

ART UNIT

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

DETAILED ACTION

Drawings

1. The drawings were received on June 18 2008. These drawings are acceptable.

Claim Objections

2. Claims 27 and 31-33 are objected to because of the following informalities:
Claim 27 recites the limitation "the surface capillary fibers" in line 2. Claim 31 recites the limitation "the surface capillary fibers" in lines 1-2. There is insufficient antecedent basis for this limitation in these claims. The word "capillary" is misspelled in line 2 of claim 33.

Appropriate correction is required.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 20, 25-31, 33-37, and 47 are rejected under 35 U.S.C. 102(b) as being anticipated by Deniega et al (U.S. Patent No. 6,350,253). In Figure 6, Deniega et al show a medical device (52) with a surface capillary fiber (54). In lines 47-63 of column 9, Deniega et al disclose a quantity of bioactive agent associated with the surface

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capillary fiber. The surface capillary fiber is considered to have a surface area of at least about a factor of 1.5 greater than a corresponding circular fiber with an equivalent diameter. The device is configured for placement within a blood vessel without blocking flow through the vessel. The device comprises a catheter and the surface capillary fibers are associated with the inner surface of the catheter as seen in Figure 6. As to claim 28, Deniega et al disclose a tubular medical device (52) comprising a tubular substrate having an interior surface, an exterior surface, and at least one surface capillary fiber associated with at least a portion of one of the surfaces where the at least one surface capillary fiber is associated with a bioactive agent. The tubular medical device is a catheter or a microcatheter. As to claim 34, Deniega et al disclose a medical device (52) comprising a non-porous surface where at least a portion of the surface is covered with surface capillary fibers which are associated with a bioactive agent. The non-porous surface comprises a polymer (lines 1-6 of column 9) and is contoured to match a portion of a structure within a patient. As to claims 47, Deniega et al disclose a method for delivering a bioactive agent where a patient's body fluids/tissues contact a surface capillary fiber associated with the bioactive agent (lines 47-63 of column 9).

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 21, 22, 24, 32, and 52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Deniega et al in view of DiCarlo et al (U.S. Patent No. 6,929,626). Deniega et al disclose the device and method substantially as claimed. Even though Deniega et al disclose a bioactive agent or medication associated with the surface capillary fiber(s), Deniega et al are silent as to the specifics of the bioactive agent being a thrombolytic agent such as heparin sulfate or a microbial agent. DiCarlo et al disclose a medical device (10) with SCF fibers (18, 22) where a bioactive agent is associated with the surface capillary fibers (lines 1-23 of column 13). DiCarlo et al disclose the bioactive agent comprising a thrombolytic agent, a microbial agent, or heparin sulfate (lines 24-44 in column 13). It would have been obvious to one having ordinary skill in the art at the time the invention was made to use as the bioactive agent of Deniega et al a thrombolytic agent such as heparin sulfate or a microbial agent as taught by DiCarlo et al as both Deniega et al and DiCarlo et al disclose medical devices with surface capillary fibers and a bioactive agent associated with the surface capillary fibers and DiCarlo et al teach that it is well known to use a thrombolytic agent such as heparin sulfate or a microbial agent for the bioactive agent which is being delivered into the patient's body.

7. Claim 23 is rejected under 35 U.S.C. 103(a) as being unpatentable over Deniega et al in view of Samson et al (U.S. Patent No. 6,066,149). Deniega et al disclose the device and method substantially as claimed. Even though Deniega et al disclose a bioactive agent or medication associated with the surface capillary fiber(s), Deniega et al are silent as to the specifics of the bioactive agent comprising tissue plasminogen

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activator (tPA). Samson et al disclose using a medical device or catheter to deliver bioactive agents such as tPA or urokinase (lines 19-27 of column 5) which are thrombolytic agents. It would have been obvious to one having ordinary skill in the art at the time the invention was made to use as the bioactive agent of Deniega et al a thrombolytic agent such as tPA as taught by Samson et al as both Deniega et al and Samson et al disclose medical device for delivering a bioactive agent and Samson et al teach that it is well known to use a thrombolytic agent such as tPA for the bioactive agent which is being delivered into the patient's body.

Response to Arguments

8. Applicant's arguments filed June 18 2008 have been fully considered but they are not persuasive.

a. As to Applicant's arguments/remarks in lines 7-10 of page 12 that the elected species covers the subject matter of claim 50, it should be noted that claim 50 depends on claim 49 which is drawn to the nonelected species Figures 9A and 9B. Therefore, it is the Examiner's interpretation that claim 50 also is drawn to the nonelected species Figures 9A and 9B.

b. As to Applicant's arguments in lines 1-19 of page 14, Deniega et al does disclose a structure that can be seen as a surface capillary fiber. The surface capillary fiber (54) of Deniega et al is disclosed as a tubular porous membrane which is a hollow fiber. Therefore, the tubular porous membrane of Deniega et al is a surface capillary fiber as the hollow fiber is a capillary fiber. Additionally, in

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response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., the surface capillary fiber having a surface structure that forms the surface capillaries) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). As to Applicant's arguments with regards to claim 34, at least a portion of the medical device of Deniega et al has a non-porous surface which is the portion of the surface shown at 52 on the right hand side of Figure 6.

Therefore, the medical device has a non-porous surface where at least a portion of the surface is covered with surface capillary fibers.

c. As to Applicant's arguments in lines 4-18 of page 15, Deniega et al does disclose a structure that can be seen as a surface capillary fiber and, thus, teach all of the elements in the independent claims. As to the disclosure of DiCarlo et al of a surface capillary fiber, the textile material of DiCarlo et al is a fiber which when woven or braided can form surface capillaries. Therefore, both Deniega et al and DiCarlo et al do teach surface capillary fibers.

Conclusion

9. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE

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MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BHISMA MEHTA whose telephone number is (571)272-3383. The examiner can normally be reached on Monday through Friday, 7:30 am to 3:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Simons can be reached on 571-272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Examiner, Art Unit 3767

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